



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 10, 2015

Jayne Walz
Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Add statement
“See side panel for First Aid and additional precautionary statements”
Product Name: VectoLex WDG Biological Larvicide Water Dispersible Granule
EPA Registration Number: 73049-57
Application Date: May 13, 2015
OPP Decision Number: 510969

Dear Ms. Walz:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

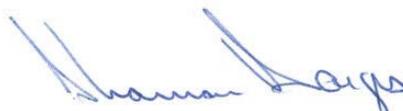
The labeling submitted with this application has been stamped “Notification” and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance Assurance.

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If you have any questions, please contact Nicola Steinmetz of my team by phone at (703) 347-8567 or via email at steinmetz.nicola@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Shannon Borges".

Shannon Borges, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

NOTIFICATION

73049-57

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/10/2015

**VECTOLEX® WDG
BIOLOGICAL LARVICIDE
WATER DISPERSIBLE GRANULE**

Active Ingredient:

Bacillus sphaericus 2362, Serotype H5a5b, Strain ABTS 1743 fermentation solids, spores and insecticidal toxins.....51.2% w/w
 Other Ingredients.....48.8% w/w
 Total.....100.0% w/w

Potency: This product contains 650 BsITU/mg or 0.299 Billion BsITU/lb.

The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See side panel for First Aid and additional precautionary statements.

Produced For:
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

EPA Reg. No. 73049-57
EPA Est. No. 33762-IA-1

Batch Code:_____

Net Weight:

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open, and rinse slowly and gently with water for 15 - 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-315-9819 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-323-9597.	

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Causes moderate eye irritation. Harmful if inhaled. Avoid contact with eyes or clothing and breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Mixer/loaders and applicators not in enclosed cabs or aircraft must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

ENVIRONMENTAL HAZARDS

Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

CHEMIGATION

Do not apply this product through any type of irrigation system.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage:

Store in cool [59-86° F (15-30° C)], dry place.

Pesticide Disposal:

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPLICATION DIRECTIONS

VectoLex[®] WDG Biological Larvicide Water Dispersible Granule (hereafter referred to as VectoLex WDG) is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoLex WDG can be applied to areas that contain fish, other aquatic life and plants. VectoLex WDG can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife.

Do not apply when wind speed favors drift beyond the area of treatment.

I. For control of mosquito larvae species* in the following non-crop sites:

<u>Habitats</u>	<u>Application Rate Range</u>
Wastewater: Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons and impounded wastewater associated with fruit and vegetable processing	0.5-1.5 lbs/acre (8-24 oz/acre)
Stormwater/Drainage Systems: Storm sewers, catch basins, drainage ditches, retention ponds, detention ponds and seepage ponds	0.5-1.5 lbs/acre (8-24 oz/acre)
Marine/Coastal Areas: Salt marshes, mangroves and estuaries	0.5-1.5 lbs/acre (8-24 oz/acre)
Water Bodies: Natural and manmade aquatic sites such as lakes, ponds, rivers, canals and streams	0.5-1.5 lbs/acre (8-24 oz/acre)
Dormant Rice Fields: Impounded water in dormant rice fields (For application ONLY during the interval between harvest and preparation of the field for the next cropping cycle)	0.5-1.5 lbs/acre (8-24 oz/acre)

II. For control of mosquito larvae species* in the following agricultural/crop sites where mosquito breeding occurs:

<u>Habitats</u>	<u>Application Rate Range</u>
Rice, pastures/hay fields, orchards, citrus groves and irrigated crops	0.5-1.5 lbs/acre (8-24 oz/acre)

Use higher application rates (1 - 1.5 lbs/acre or 16 – 24 oz/acre) in areas where extended residual control is necessary, or in habitats having deep water or dense surface cover.

Apply uniformly by aerial or conventional ground application equipment. Reapply as needed after 1-4 weeks.

*Mosquito species effectively controlled by VectoLex WDG:

Culex spp.

Aedes vexans

Ochlerotatus melanimon (*Aedes melanimon*)

Ochlerotatus stimulans (*Aedes stimulans*)

Ochlerotatus nigromaculis (*Aedes nigromaculis*)

Psorophora columbiae

Psorophora ferox

Ochlerotatus triseriatus (*Aedes triseriatus*)

Ochlerotatus sollicitans (*Aedes sollicitans*)

Anopheles quadrimaculatus

Coquillettidia perturbans

GROUND AND AERIAL APPLICATION

VectoLex WDG may be applied using conventional ground or aerial application equipment with quantities of water sufficient to provide uniform coverage of the target area. For application, first add the VectoLex WDG to water to produce a final spray mixture.

The amount of water needed for application will depend on weather, spray equipment, and mosquito habitat characteristics. For application, fill the mix tank or plane hopper with the desired quantity of water. **Start the mechanical or manual agitation to provide moderate circulation of water before adding VectoLex WDG.** Backpack and compressed air sprayers may be agitated by shaking after adding VectoLex WDG to the water in the sprayer. VectoLex WDG suspends readily in water and will stay suspended over normal application periods. Brief recirculation may be necessary if the final spray mixture has sat for several hours or longer. Do not mix more VectoLex WDG than can be used in a 48-hour period. **AVOID CONTINUOUS AGITATION OF THE FINAL SPRAY MIXTURE DURING SPRAYING.**

For ground application, apply 0.5-1.5 lbs or 8-24 oz (227-680 g) of VectoLex WDG in 5-100 gallons of water per acre using hand-pump, airblast, mist blower, or other spray equipment. For aerial application, apply 0.5-1.5 lbs or 8-24 oz (227-680 g) of VectoLex WDG per acre through fixed wing or helicopter aircraft equipped with either conventional boom and nozzle systems or rotary atomizers at a convenient dilution rate. For aerial application, apply 0.5-10 gal of the final spray mixture per acre to provide uniform coverage of the target area.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determines the potential spray drift. The applicator and treatment coordinator are responsible for considering all these factors.

Rinse and flush spray equipment thoroughly following each use.

Amount of VectoLex WDG needed to treat small areas:

Area to Treat	Application Rate of VectoLex WDG/Acre		
	0.5 lb (8 oz)	1 lb (16 oz)	1.5 lb (24 oz)
¼ Acre	0.125 lb (2 oz)	0.25 lb (4 oz)	0.375 lb (6 oz)
½ Acre	0.25 lb (4 oz)	0.5 lb (8 oz)	0.75 lb (12 oz)
10 Acres	5 lb (80 oz)	10 lb (160 oz)	15 lb (240 oz)
20 Acres	10 lb (160 oz)	20 lb (320 oz)	30 lb (480 oz)

NOTICE TO USER

To the extent consistent with applicable law, Seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on this label. To the extent consistent with applicable law, User assumes all risks of use, storage or handling not in accordance with accompanying directions.

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